OBJECTIVES: The importance of patient-centered outcomes (PCO) in drug development is increasingly recognized by health authorities, clinical advisory and patient advocacy bodies. Accordingly, many of these organizations seek to include PCO in their guidelines and recommendations. However, complex disorders present measurement challenges that are difficult to resolve within the scope of a clinical trial (CT). An example is Systemic Lupus Erythematosus (SLE), characterized by myriad clinical indicator, symptom, severity and frequency combinations. SLE patient burden studies demonstrate that, while symptoms differ, the impact is universal. This study evaluates the relationship between recently updated SLE guidances and concepts reported directly by SLE patients. **METHODS:** A qualitative study comprised of six SLE patient focus groups (N=43) was conducted to elicit direct patient input on key symptoms and concepts. FDA and EMA guidelines for SLE clinical trials, European League Against Rheumatism (EULAR) CT endpoint recommendations, and the Systemic Lupus International Collaborating Clinics (SLICC) classification system were evaluated for PCO-specific content. Patient-reported outcomes (PRO) concepts from the study were then compared to the PCO content from the guidelines and recommendations. **RESULTS:** All study subjects (mean age 44.3 years; 91.7% women; 63% diagnosed ≥ 5 years; 91% experienced flare ≤ 3 months; 74% mild/moderate disease) identified fatigue among "most important symptoms" with 98% citing pain and 44% fog/confusion. Regardless of "importance" all subjects deemed other symptoms highly disruptive. EMA and FDA both specify fatigue as a clinical trial endpoint. FDA included "fatigue" based on clinician input, but recommended development of a PRO-based fatigue exploratory endpoint. EULAR, citing challenges of symptom endpoints, suggested general Health-Related Quality of Life. The SLICC didn't mention PCOs. **CONCLUSIONS:** Patients identified multiple SLE symptoms and impacts, yet guidances didn't address these issues. Joint efforts between patients, sponsors, regulators and advisory organizations are necessary to implement relevant PCOs, especially in complex disorders.

PSY62

COMPARISON OF CLINICAL AND COST CHARACTERISTICS AMONG PATIENTS WITH INFLAMMATORY BOWEL DISEASE ACROSS DIFFERENT SITES OF CARE

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OBJECTIVES: To compare clinical and cost characteristics among patients with inflammatory bowel disease (IBD) receiving biologic medication in an in-office setting (IOI), hospital outpatient department (HOPD), or ambulatory clinic. **METHODS:** A syndicated study of IBD patients was conducted. Patients aged ≥18 years were recruited via the National Health and Wellness Survey and Lightspeed Research Panel to complete a survey during August–November 2010. Patients were asked about health care utilization, concomitant medications, IBD symptoms, quality of life (QoL) and out-of-pocket (OOP) costs. To measure utilization, the number of provider, emergency room (ER), and hospital visits in the past 6 months was collected. The Medical Outcomes Study (MOS) IBD questionnaire was used to assess QoL. Bivariate differences were assessed using Fisher's exact tests for categorical variables and ANOVAs for continuous variables. **RESULTS:** Of 175 IBD patients, 54% (n=94) received biologic medication in an IOI setting, 35% (n=61) in an HOPD setting, and 11% (n=20) in an ambulatory clinic. The number of ER and hospital visits were similar across groups, however IOI patients had greater provider visits ($p<0.05$). Though concomitant medication utilization was generally similar, significantly more IOI patients received steroids compared to HOPD patients ($p<0.05$). Most IBD symptoms did not differ across groups. However, HOPD patients were more likely to have fistulas than IOI patients (30% vs. 16%; $p<0.05$), and IOI patients were less likely to experience bowel movements than HOPD or clinic patients (55% vs. 84% and 80%, respectively). HOPD patients had lower OOP costs for biologic medications and higher QoL scores compared to IOI patients ($p<0.05$). **CONCLUSIONS:** Among IBD patients receiving biologic medication in an IOI, HOPD, or ambulatory clinic setting, HOPD patients had higher QoL and lower OOP costs, however, few other differences were identified. Further research is needed to elucidate these findings.

PSY64

CORRELATES OF IMPROVEMENT IN PHYSICAL QUALITY OF LIFE AND QUALITY OF SLEEP AMONG CHRONIC LOW BACK PAIN PATIENTS WITH TREATMENT WITH BUPRENORPHINE TRANSDERMAL SYSTEM (BTDS)

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OBJECTIVES: Deficits in physical health-related quality of life (HRQL) and sleep quality in chronic low back pain (CLBP) patients may be alleviated with Buprenorphine Transdermal System (BTDS) treatment. This post-hoc analysis of clinical trial data aimed to explore whether BTDS treatment has a direct impact on HRQL and sleep quality, an indirect impact on the outcomes as mediated through its impact of pain, or both; and to identify significant correlates of HRQL and sleep quality. **METHODS:** In this multicenter, enriched, double-blind, randomized trial, opioid-naïve patients with moderate-to-severe CLBP received twelve weeks' treatment with BTDS (10 or 20 mcg/hour) or placebo. A series of multivariate linear regression models (stepwise) predicting physical HRQL, sleep disturbance, and sleep quality at week 12 were fitted. Physical HRQL was measured using the SF-36v2 Physical Component Summary (PCS), while sleep outcomes were measured using the Disturbance subscale and Sleep Problems Index (SPI) of the Medical Outcomes Study Sleep Scale (MOS-SS). For each outcome, models 1 and 2 included baseline demographic and clinical variables, model 3 added treatment arm, and model 4 added pain assessment at week 8. **RESULTS:** Results from model 3 supported BTDS treatment as a significant predictor of better physical HRQL and sleep outcomes. Model 4 results for each outcome indicated that pain was a partial mediator of treatment on physical HRQL and sleep quality, meaning that treatment had both direct and indirect effects on these outcomes. Mid-trial pain and the baseline value of the outcome being tested (i.e., PCS score, Disturbance score, or SPI score) were the strongest predictors for each outcome. **CONCLUSIONS:** For CLBP patients, improvements in physical HRQL, sleep disturbance, and sleep quality were impacted by BTDS treatment both directly as well as indirectly via mediation through the treatment-driven reductions in pain. Mid-trial pain strongly predicted to HRQL and sleep outcomes.

PSY65

RESPONSIVENESS AMONG PATIENT-REPORTED MEASURES OF QUALITY OF LIFE, QUALITY OF SLEEP, AND FUNCTIONAL DISABILITY TO PAIN AND IMPACT OF BUPRENORPHINE TRANSDERMAL SYSTEM (BTDS) TREATMENT IN CHRONIC LOW BACK PAIN PATIENTS

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OBJECTIVES: Patients with moderate-to-severe chronic low back pain (CLBP) who are treated with Buprenorphine Transdermal System (BTDS) experience improvements in three patient-reported outcomes: quality of life (QoL), sleep quality, and functioning. This analysis compared the relative responsiveness of measures of each outcome to treatment and treatment-driven changes in pain. **METHODS:** This post-hoc analysis used data from an enriched, 12-week double-blind, randomized placebo-controlled trial evaluating BTDS (10 or 20 mcg/hour) for treatment of pain in opioid-naive patients with moderate-to-severe CLBP. The trial repeatedly assessed QoL (SF-36v2), sleep quality and problems (Medical Outcomes Study Sleep Scale [MOS-SS]), and functional disability (Oswestry Disability Index [ODI]) in addition to measures of pain. Responsiveness of each instrument to treatment and changes in pain were examined using analysis of covariance, t-tests, and effect sizes for comparison of effects of time, treatment, and magnitude of pain reduction. The interrelation among PROs was also examined. **RESULTS:** The SF-36v2 and ODI showed better responsiveness to treatment and changes in pain than did the MOS-SS. Among subscales of the MOS-SS, only Disturbance showed substantial correlations with other PRO and pain measures and substantial differences across time, treatment, and pain reduction status groups. Several of the QoL domains measured by the SF-36v2, particularly Bodily Pain, Physical Functioning, Role Physical, Social Functioning, and Vitality, showed considerable responsiveness to treatment and pain. For the ODI, the Pain Intensity subscale showed the greatest responsiveness, with the majority of the remaining subscales showing more moderate, but still meaningful, levels of responsiveness. PRO measures were, in general, moderately inter-correlated, particularly between SF-36v2 and ODI subscales. **CONCLUSIONS:** Pain subscales on the SF-36v2 and ODI showed the greatest responsiveness to treatment. Substantial responsiveness was also observed for the majority of QoL and functioning domains, as well as sleep disturbance. Subscales of PRO instruments were generally moderately inter-correlated.

PSY66

CONTENT VALIDITY OF A NEW OBESITY-SPECIFIC HEALTH RELATED QUALITY OF LIFE (HRQOL) INSTRUMENT – FABQOL

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OBJECTIVES: Obesity has become a major public health problem worldwide. In Singapore, the prevalence of obesity among adults aged 18-69 years increased from 6.9% in 2004 to 10.8% in 2010. To the best of our knowledge, no single obesity-specific HRQoL instrument comprehensively covered areas of life that are important to obese individuals. Therefore we sought to assess the content validity of FABQOL, a newly developed instrument, to address the gap. **METHODS:** FABQOL (76 items) was developed based on literature review and mapped to obesity-specific International Classification of Functions Disability and Health (ICF) categories. Content validity (i.e. item comprehension and content coverage) was assessed through individual cognitive debriefing interviews with 30 English-speaking, ethnic Chinese, Malay and Indian overweight/obese patients from a weight management clinic at a public hospital in Singapore. For each item, we asked participants if the item was important to them (yes/no). Items that were perceived as not important by at least 50% of the participants and items that were not understood by at least 20% of the participants were removed. Participants were also asked to suggest additional items that were important. **RESULTS:** Participants aged from 23-58 years (median age = 45), one-third were men and 90% were obese (BMI>27.5kg/m^2). Two items "being able to eat as much as I want to" and "being able to reach for objects placed above me" were perceived as not important by 26 (87%) and 15 (50%) of participants respectively. Four items ("lethargic", "distressed", "anxious" and "stigmatized") were removed because they were poorly understood. Three participants suggested three new items pertaining to relationship with close friends, company image and personal leisure activities. **CONCLUSIONS:** The revised FABQOL comprises 73 items that were generally easy to understand and important to overweight/obese patients in Singapore. Psychometric properties of FABQOL will be evaluated in a larger study.

PSY67

LONGITUDINAL CHANGES IN HEALTH-RELATED QUALITY OF LIFE FOR CHRONIC DISEASES: AN EXAMPLE FROM THE HEMOPHILIA UTILIZATION GROUP STUDY PART VA (HUGS VA)

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